ROWE WEINSTEIN & SOHN PLLC
Attorneys and Counselors at Law

June 5, 2020

The Honorable Theodore D. Chuang
UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
6500 Cherrywood Lane
Suite 245A
Greenbelt, MD 20770

Re: **American College of Obstetricians & Gynecologists et al.**
v. United States Food and Drug Administration et al, Case No. 8:20-cv-1320-TDC
Notice of Intent to File Motion to Intervene of Right by the State of Indiana, the State of Nebraska, the State of Louisiana, and the State of Oklahoma

Dear Judge Chuang:

Pursuant to the Court's Case Management Order dated May 28, 2020 herein, we respectfully hereby give notice of our intent to file a motion to intervene as party defendants on behalf of our clients, the States of Indiana, Nebraska, Louisiana, and Oklahoma, and possibly on behalf of additional states that may join this coalition.

The Proposed Intervenors (hereinafter, "the States") have met and conferred with counsel for all parties in this suit: Plaintiffs intend to oppose the States' motion, while Defendants intend to take no position on the motion. The States now seek a pre-motion conference with the Court.

Indiana will move to intervene in this case as a matter of right under Rule 24(a): the State has a direct and substantial interest in the enforceability of its own laws, which rely on the FDA REMS challenged here, this interest will be impaired if the State is not allowed to intervene, and FDA does not adequately represent the interest. Moreover, the State's motion is timely, as the lawsuit was filed on May 27, 2020, and the deadlines to identify witnesses and respond to Plaintiffs' motion for preliminary injunction are set for June 8 and June 10, 2020. The State intends to comply with those deadlines. In the alternative, the State will argue that it should be permitted to intervene under Rule 24(b).

Indiana has a direct and substantial interest in the enforceability of its abortion laws, which directly rely on the mifepristone REMS. Indiana Code section 16-34-2-1 provides that "an abortion inducing drug may not be dispensed, prescribed, administered, or otherwise given to a pregnant woman after nine (9) weeks of postfertilization age unless the Food and Drug Administration has approved the abortion inducing drug to be used for abortions later than nine (9) weeks of postfertilization age." Ind. Code § 16-34-2-1(a)(1). It further states that "[a] physician shall examine a pregnant woman in person before prescribing or dispensing an abortion inducing drug." Id. Also in accordance with FDA guidelines, the physician must "provide the pregnant woman with a copy of the manufacturer's instruction sheets and require that the pregnant woman sign the manufacturer's patient agreement form." Id. The statute specifically provides that "'in person' does not include the use of telehealth or telemedicine services." Id.

Section 16-34-2-1 enshrines in state law the Mifepristone In-Person Dispensing Requirement that Plaintiffs challenge in this case. If this Court holds that the federal in-person dispensing requirement must be enjoined as applied during the COVID-19 pandemic, then the State requirements for in-person dispensing would be in question as well. Yet in the absence of the in-person requirement, Indiana will

have no way of protecting its citizens against the harms that can come from the unsupervised administration of medication abortion drugs. Moreover, because the Indiana statute relies so heavily on the REMS, the outcome of this case will raise questions about how the statute should be interpreted, and more specifically, which parts of the statute may no longer be valid if the REMS is enjoined.

Indiana and the other Proposed Intervenors also have a direct and substantial interest in protecting their citizens by ensuring mifepristone is administered in a safe manner. Mifepristone can cause serious complications, such as hemorrhage, infection, and death. While such complications are always a possible result of mifepristone-induced abortion, the chances that a complication will occur increase significantly in women for whom mifepristone is contraindicated. For instance, mifepristone is highly dangerous for a woman who has an ectopic pregnancy or for a woman who is past the approved gestational time frame. Without an in-person examination, the physician would have no way of determining whether mifepristone can be safely prescribed to a particular patient.

Moreover, an in-person meeting between the patient and the doctor facilitates informed consent and protection of women from exploitation. A woman may feel more comfortable asking questions of a doctor who takes the time to meet with her in person. The doctor will be better able to assess the woman's consent and identify possible coercion. Even a video call could not prevent a partner, parent, or other individual from being in the same room with the woman and pressuring her abortion decision. And mail or online order would elevate this risk even more: a trafficker could purchase several doses of mifepristone and either force unwilling women to take the pill or resell the pills on the black market. Indiana and the other States clearly have an interest in preventing such calamities. In-person interactions provide vulnerable women an opportunity to withhold consent or report exploitation that might not otherwise be available—and opportunity that is especially important in a time of isolation and social distancing.

The Proposed Intervenors' interests will be impaired if it is not allowed to intervene in this lawsuit. Because relevant Indiana state law relies on FDA standards, any ruling that would block FDA's in-person dispensing requirement would necessarily implicate the relevant Indiana laws. If Indiana cannot intervene in this action, it will be impaired in defending against an action that threatens to render its own laws unenforceable (including at least one such challenge now pending). In turn, if intervention is not allowed, all Proposed Intervenors will be impaired in their ability to adequately protect the interests of their citizens from the increased health and other risks that will result from unsupervised administration of mifepristone. In turn, complications from these health risks may put a burden on Proposed Intervenors' Medicaid systems, increasing the cost to taxpayers.

FDA cannot adequately represent these broad state interests. FDA has a much narrower institutional interest: providing guidelines for the safe approval and administration of drugs. But it does not share the States' broader interests in regulating the practice of medicine, protecting human life by ensuring that the abortion decision is properly informed, and protecting health and safety by preventing the illegal trafficking of both drugs and humans. At a minimum, FDA does not adequately represent a State's interest in enforcing its own laws. If Proposed Intervenors are not allowed to intervene, these interests will go unrepresented.

1401 Rockville Pike, Suite #110, Rockville, MD 20852
Telephone: 301-770-4710 / Facsimile: 301-770-4711

For these reasons, the States respectfully request that the Court set a pre-motion conference and allow them to file a motion to intervene setting forth their grounds more thoroughly.

Respectfully submitted,

/s/ Alexander A. Bush
Alexander A. Bush
Rowe Weinstein & Sohn, PLLC
1401 Rockville Pike, Suite #110
Rockville, MD 20852